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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,137	06/28/2000	Michael E. Moseley	500.003US1	5608

7590 02/16/2010

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ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
02/16/2010	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/606,137
Filing Date: June 28, 2000
Appellant(s): MOSELEY ET AL.

Mark A. Litman (Reg. No. 26,390)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/5/09 appealing from the Office action mailed 5/15/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,869,463	MAJOR et al.	2-1999
5,497,770	MORCOS et al.	3-1996
6,567,684	CHENEVERT et al.	5-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 5, 6, 13, 14, 17, 18, 20, 21, 25, 26, 54, 55, 57, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Major et al. (5869463). Major et al. disclose a method for indicating viability of transplanted progenitor or stem cells grown in a culture (col. 5 lines 31-67, col. 6 lines 1-16). The method involves non-destructively observing a region of a patient to where progenitor or stem cells grown in a culture have been transplanted (col. 7 lines 33-41). The method involves sensing a property within the region of a patient that is indicative of cell viability or inviability of the transplanted progenitor or stem cells using magnetic resonance imaging (col. 11 lines 28-36) where cell viability is indicated by a property in cell chemistry resulting from an event such as cell activity/inactivity, cell growth/death, specific cell function/dysfunction, volumetric expansion of cell population, and volumetric decrease of cell population (col. 4 lines 7-14). The sensing of a property within said region of a patient that is indicative of cell viability or inviability of the implanted colony of cells is used to quantitate the cell viability (col. 4 lines 16-67). Different properties of the transplanted cells are measured and would necessarily involve monitoring tissue blood flow or changes in blood flow as vascular supply is developed and where T1 and T2 weighted images with and without contrast agent are generated (col. 11 lines 32-36). Properties such as tissue density are measured (col. 7 lines 10-23, col. 9 lines 53-61).

2. Claims 7, 9, 11, 12, 15, 16, 19, 22, 29, 56, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Major et al. in view of Morcos et al. (5497770). Major et al. disclose a method for indicating viability of transplanted progenitor or stem cells grown in a culture (col. 5 lines 31-67, col. 6 lines 1-16). The method involves non-destructively observing a region of a patient to where progenitor or stem cells grown in a culture have been transplanted (col. 7 lines 33-41). The method involves sensing a property within the region of a patient that is indicative of cell viability or inviability of the transplanted progenitor or stem cells using magnetic resonance imaging (col. 11 lines 28-36) where the system would necessarily include a volume coil surrounding the tissue and a local multi-tuned MRI RF coil. Cell viability is indicated by a property in cell chemistry resulting from an event such as cell activity/inactivity, cell growth/death, specific cell function/dysfunction, volumetric expansion of cell population, and volumetric decrease of cell population (col. 4 lines 7-14). The sensing of a property within said region of a patient that is indicative of cell viability or inviability of the implanted colony of cells is used to quantitate the cell viability (col. 4 lines 16-67). Different properties of the transplanted cells are measured and would necessarily involve monitoring tissue blood flow or changes in blood flow as vascular supply is developed and where T1 and T2 weighted images with and without contrast agent are generated (col. 11 lines 32-36).

Major et al. teach monitoring the viability of the transplanted cells, as stated previously, but do not teach specifically monitoring one of the parameters such as lactate level, local glucose turnover, local phosphorous high-energy metabolite

concentration, local F-19 labeled metabolites, alterations in tissue sodium, or changes in the conversion rates of oxygen gas to water. In the same field of endeavor Morcos et al. disclose a method for monitoring tissue viability of transplanted cells by monitoring glucose uptake (col. 9 lines 1-35). Morcos et al. teach measuring various parameters with respect to cell viability including gangrenous or necrotic tissue, muscle or connective tissue, tissues associated with atherosclerosis or clots or trauma and would necessarily involve monitoring blood flow or changes in blood flow as vascular supply is developed (col. 14 lines 57-65). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Morcos et al. to modify the teaching by Major et al. for the purpose of effectively measuring tissue viability (col. 14 lines 41-44).

3. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Major et al in view of Chenevert et al. (6567684). Major et al. disclose a method for indicating viability of transplanted progenitor or stem cells grown in a culture (col. 5 lines 31-67, col. 6 lines 1-16). The method involves non-destructively observing a region of a patient to where progenitor or stem cells grown in a culture have been transplanted (col. 7 lines 33-41). The method involves sensing a property within the region of a patient that is indicative of cell viability or inviability of the transplanted progenitor or stem cells using magnetic resonance imaging (col. 11 lines 28-36) where cell viability is indicated by a property in cell chemistry resulting from an event such as cell activity/inactivity, cell growth/death, specific cell function/dysfunction, volumetric expansion of cell population, and volumetric decrease of cell population (col. 4 lines 7-14). The sensing of a property within said region of a patient that is indicative of cell viability or inviability of the

implanted colony of cells is used to quantitate the cell viability (col. 4 lines 16-67). Different properties of the transplanted cells are measured and would necessarily involve monitoring tissue blood flow or changes in blood flow as vascular supply is developed and where T1 and T2 weighted images with and without contrast agent are generated (col. 11 lines 32-36). Properties such as tissue density are measured (col. 7 lines 10-23, col. 9 lines 53-61).

Major et al. do not explicitly teach monitoring anisotropic water diffusion. In the same field of endeavor Chenevert et al. disclose method of monitoring anisotropic water diffusion of transplanted cells (col. 2 lines 10-41). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Chenevert et al. to modify the teaching by Major et al. for the purpose of determining the effectiveness of an organ or a tissue transplant (col. 3 lines 1-12).

4. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Major et al. in view of Dinsmore. Major et al. teach measuring or monitoring various parameters to determine tissue viability but do not teach measuring local concentrations of choline, NAA, GABA, phosphocholine, or creatine. In the same field of endeavor Dinsmore disclose a method of measuring properties of transplanted cells including measuring concentration of GABA (col. 27 lines 37-54). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Dinsmore to modify the teaching by Major et al. for the purpose of effectively measuring viability of transplanted cells post-transplantation.

(10) Response to Argument

With respect to the viability of cells post-implantation, Major et al. teach, as stated previously, various properties are evaluated such as graft rejection, inflammation response, and tumor formation of the transplanted cells in a patient post-transplantation (col. 4 lines 7-15). Major et al. clearly state that the transplanted cells have been shown to induce neuron migration and neurite extension demonstrating that the cells are functioning and therefore demonstrating cell viability in a patient post-transplantation. With respect to the use of MR imaging to evaluate cell properties, example 4 clearly teaches conducting an MR evaluation in a patient post-transplantation checking for tumor growth and this would necessarily also mean checking for the viability of the transplanted cells since the cells were implanted to inhibit tumor formations. Major et al. teach conducting this evaluation one month following implantation and applicant states that this MR evaluation must be done within a certain time-frame post implantation. However the claims directed to MR sensing are not limited to conducting the sensing step within a certain time frame post transplantation.

While Major et al. do teach in-vitro analysis of the cells pre-implantation, the reference is directed to testing the functionality or non-functionality of the transplanted cells post-implantation using various sensing systems including MRI evaluation.

With respect to the quantitative assessment of functionality, Major et al. teach MR evaluation and obtaining T1 and T2 weighted images with and without contrast and therefore shows blood flow changes in the cells and necessarily provides a quantitative assessment of the transplanted cells. The disclosure in Major et al. is directed to

implantation of stem cells into patients for therapeutic purposes and checking the functionality of cells post transplantation.

With respect to Morcos et al., the reference discloses a method for monitoring tissue viability of transplanted cells by monitoring glucose uptake (col. 9 lines 1-35). Morcos et al. teach measuring various parameters with respect to cell viability including gangrenous or necrotic tissue, muscle or connective tissue, tissues associated with atherosclerosis or clots or trauma and would necessarily involve monitoring blood flow or changes in blood flow as vascular supply is developed (col. 14 lines 57-65). While Major et al. do teach measure the functionality of cell post-implantation, the reference does not explicitly teach measuring parameters such as glucose levels in the cells. It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Morcos et al. to modify the teaching by Major et al. for the purpose of effectively measuring tissue viability (col. 14 lines 41-44) where the disclosure in Morcos et al. can be used to monitor the viability of organs after a transplant.

With respect to Chenevert et al., a method is disclosed for monitoring anisotropic water diffusion of transplanted cells (col. 2 lines 10-41). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Chenevert et al. to modify the teaching by Major et al. for the purpose of determining the effectiveness of an organ or a tissue transplant (col. 3 lines 1-12).

With respect to Dinsmore, a method is disclosed for measuring properties of transplanted cells including measuring concentration of GABA (col. 27 lines 37-54). It would have therefore been obvious to one of ordinary skill in the art to use the teaching

by Dinsmore to modify the teaching by Major et al. for the purpose of effectively measuring viability of transplanted cells post-transplantation.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Baisakhi Roy

/Baisakhi Roy/

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